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Released: December 19, 2023

**To:** Medical Cannabis Policy Advisory Board

From: Cannabis Research Review Board

Subject: CMC API with OME/poison control

#### Introduction

The board should consider the following questions about medical cannabis database integration with other state health monitoring programs:

- 1. Should lawmakers amend the Utah code to allow for application programming interface (API) integration between the medical cannabis electronic verification system (EVS) database and the Office of the Medical Examiner (OME), Utah Poison Control Center (UPCC) databases and/or Department of Public Safety traffic records to improve patient safety and product quality by improving adverse event (AE) reporting?
- **2.** If so, what requirements should apply?

## **Background**

Identifying AEs caused by Utah medical cannabis products can be challenging as reporting offices cannot confirm if the affected individual is a participant in the medical cannabis program or uses cannabis products outside the program. Integrating the API with the EVS and OME/UPCC/DPS databases can help improve the state's ability to determine if a Utah medical cannabis product is involved in an AE. The API would enable public health partners to verify whether the patient has an active medical cannabis card, similar to the controlled substance (CSD) or Utah Criminal Justice Information System (UCJIS) databases.

# **Analysis**

Ensuring patient safety and improving healthcare quality heavily relies on reporting adverse events. A report by the World Health Organization (WHO) in 2019 revealed that



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unsafe patient care is one of the top ten causes of death and disability (Singh et al., 2023). However, just collecting information on adverse events is not enough. To better comprehend the causes of these events and prevent them from happening again, an in-depth analysis of the adverse event through a root cause analysis (RCA) process is necessary (AHRQ, 2019a). This allows organizations to systematically understand the cause and identify any safety or quality gaps in the treatment process (AHRQ, 2019b). The ultimate goal of the RCA is to prevent the recurrence of the reported adverse event in the future by creating strategies to avoid it (Singh et al., 2023).

The RCA has two primary functions. Firstly, it creates a culture of interprofessional discussions and collaborations to improve patient safety and quality in healthcare organizations. Secondly, it uses interdisciplinary team collaboration to identify system-level causes or gaps related to AE (Singh et al., 2023).

To collect data, a significant component of the RCA process, healthcare organizations need to include anything that could be an underlying cause of the AE. The Utah Center for Medical Cannabis EVS patient registrant data is one of the necessary data sources that improve the quality of the RCA. It provides accuracy and granular details and removes the need for assumptions or unanswered questions (Singh et al., 2023).

### **Examples of other cannabis-adverse reporting**

A rapid analysis of the current state of medical cannabis AE reporting was completed by DHHS staff. Information was gathered from the review of 19 active medical cannabis programs' available websites and statutory language. If the website included an email address or contact form, we sent a link to our <u>Google form</u> and compiled email responses in a <u>spreadsheet</u>. DHHS staff also posted a request for responses in the <u>Cannabis</u> <u>Regulators Association's</u> electronic messaging forum hosted by <u>Basecamp</u>.

We received direct responses from the following 10 programs: Hawaii, Iowa, Minnesota, Nevada, New York, North Dakota, Oregon, Pennsylvania, Vermont, and West Virginia. Five additional medical cannabis program information were collected directly from their online resources. This includes Alabama, Alaska, Kentucky, Maryland, and Canada.



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The analysis revealed that Alaska was the only medical cannabis program that reported having direct API integration for AE monitoring. Alaskan code <u>17.30.200</u> requires the pharmacy or dispensary to submit a daily record of each prescription for controlled substances to the state's prescription drug monitoring program. The state offers open-sourced API software to all healthcare entities in Alaska via the <u>statewide gateway integration</u>, which is funded by grants.

Alabama, Hawaii, Maryland, Minnesota, New York, North Dakota, Pennsylvania, Texas, and Canada all have regulatory language of varying requirements for reporting medical cannabis-related AE. Many of the reporting processes include completing an electronic form that is either collected directly by the regulatory agency (prescription drug monitoring program) or a third-party reporting program (SafetyCall International).

Another third-party non-profit reporting program is known as Cannabis Adverse Risk Events (CARE). It is a division of the Foundation of Cannabis Unified Standards (FOCUS). FOCUS is a cannabis health and safety organization whose goal is to promote integrity in the cannabis industry. However, at this time, CARE does not openly report on the individual AEs or publish its collected data. In addition to reporting AEs to their healthcare provider, an individual may choose to report to the Food and Drug Agency (FDA) through their MedWatch program. However, it is important to note that voluntary, self-reported information may only sometimes be accurate due to patients or their families being afraid of legal consequences, which may result in incorrect information or the incident not being reported.

#### Patient impact

Having an integrated database to report on AEs will have a positive impact on patients for a variety of reasons. The information from the database can be used to improve product quality as patients can report on their personal experience with products. It will also allow for an improvement in patient safety as this information can be used to address any concerns with medical cannabis. Regulatory transparency will be improved due to the database fostering an environment for discussion and to report any concerns. The integrated database would allow for the sharing of health data between institutions and allow for more information to be shared to improve systems in place.



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### Industry impact

The reporting of AEs through a database will have an impact on the industry by improving the feedback loop. The database would allow for the state to identify if a Utah medical cannabis product was involved in an AE. That information could then be used to better understand the cause of these events and to make changes to prevent these events from occurring in the future.

## **Options**

- 1. Report specific incidences such as cases requiring hospitalization, medical intervention, or sentinel events when requested by OME/UPCC/DPS.
- 2. Share information about all active cards and patients who have made a purchase within the last 12 months.
- 3. Do not integrate the system with an API or share patient data.



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### **References**

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